

Please add the following claims:

~~49. (New) The defective recombinant adenovirus of claim 48, wherein part of the E1 region is deleted.~~

~~50. (New) The defective recombinant adenovirus of claim 48, wherein all of the E1 region is deleted.~~

~~51. (New) The defective recombinant adenovirus of claim 49, wherein all or part of the E3 region is deleted.~~

52. (New) The defective recombinant adenovirus of claim 50, wherein all or part of the E3 region is deleted.

#### REMARKS

##### *The Amendment to the Title*

The title of the instant application has been amended to more accurately reflect the subject matter of the pending claims. A separate document setting forth the precise changes to the title is submitted herewith.

##### *The Amendments to the Claims*

Claim 48 has been amended to point out more particularly and claim more distinctly the present invention. The amendment to claim 48 is supported by the specification at, for example, page 11, lines 26-31, page 13, lines 4-7, and page 24, line 23, through page 25, line 23. Claims 49-52 have been added, and are supported by the specification at, for example, page 24, line 23, through page 25, line 23. The amendment to claim 48 and the addition of claims 49-52 had not been proposed previously in that the amendment and additions serve to place the pending claims more in-line with those of related patent applications nearing allowance. The amendment to claim 48 and new claims 49-52 do not require additional searching by the Patent Office as the amendment and additions do not add new subject matter to the pending claims. Separate documents setting forth the precise changes to the claims, as well as the text of the pending claims, are submitted herewith.

### *The Pending Claims*

Claims 44 and 48-52 are pending. Claim 44 is directed to a plasmid comprising a reading frame ORF6 of an E4 region of an adenovirus genome, while claims 48-52 are directed to a defective recombinant adenovirus that (a) requires, for replication, complementation in *trans* of one or more essential gene functions of an E1 region and an E4 region of an adenovirus genome, and (b) comprises an adenoviral genome wherein all or part of the E1 region and the whole of the E4 region, and optionally all or part of an E3 region, is deleted from the adenoviral genome. A separate document setting forth the text of the pending claims is submitted herewith for the convenience of the Examiner.

### *The Office Action*

The Office Action sets forth the following rejections:

(a) claim 48 has been rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 9-17, 32-46, and 53-58 of U.S. Patent 5,851,806, and claims 1, 4, 7, 9-11, 14, 17, 19, 22, and 24 of U.S. Patent 5,994,106,

(b) claim 48 has been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 69-78 of U.S. Patent Application No. 09/321,797, which has been allowed,

(c) claims 44 and 48 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 19-26, 36-40, 43-56, 62-71, and 76-95 of U.S. Patent Application No. 08/258,416, and

(d) claim 48 has been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 36-38, 52, 53, 68-70, 74, and 75 of U.S. Patent Application No. 09/261,922, claims 36 and 42 of U.S. Patent Application No. 09/766,405, and/or claims 36, 39, 40, 42, 44-46, 49, 50, 52, 54, and 55 of U.S. Patent Application No. 09/934,207.

Reconsideration of these rejections is hereby requested.

### *Discussion of Obviousness-Type Double Patenting Rejections*

Claim 48 has been rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 9-17, 32-46, and 53-58 of U.S. Patent 5,851,806. Applicants submit herewith a Terminal Disclaimer with respect to U.S. Patent 5,851,806, thereby rendering the rejection moot.

Claim 48 also has been rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1, 4, 7, 9-11, 14, 17, 19,

22, and 24 of U.S. Patent 5,994,106 ("the '106 patent"). Claim 1 of the '106 patent is directed to a replication-competent adenovirus-free stock of recombinant adenoviral vector. The recombinant adenoviral vector is deficient in one or more essential gene functions of one or more regions of the adenoviral genome selected from the group consisting of the E1, E2A, and E4 regions of the adenoviral genome. Claim 4 further defines the adenoviral vector as deficient in one or more essential gene functions of the E4 region. Claim 9 further defines the adenoviral vector as deficient in three essential gene functions. The remaining '106 patent claims cited by the Patent Office define the regions in which the deficiencies are located (e.g., claims 7 and 10), characterize the cell line in which the recombinant adenoviral vector is prepared (e.g., claims 11, 14, 17, and 19), recite a system comprising the recombinant adenoviral vector (e.g., claim 22), or recite a method of preparing the recombinant adenoviral vector (e.g., claim 24).

In determining an obviousness-type double patenting rejection, the Patent Office must determine if the *claimed* invention of a patent application is in conflict with an invention *claimed* in a patent (M.P.E.P. 804). Claim 48 of the instant application is directed to a defective recombinant adenovirus wherein the *whole of the E4 region* of the adenoviral genome of is deleted. The claims of the '106 patent do not teach or suggest a complete deletion of the entire E4 region of the adenoviral genome. Nevertheless, instant claim 48 stands rejected because the Patent Office contends that the subject matter of instant claim 48 "embraces," i.e., "dominates," the subject matter of the claims of the '106 patent as directed to the adenovirus of Examples 3 and 4. "Domination" occurs when "the broader claim 'embraces' or 'encompasses' the subject matter defined by the narrower claim." *In re Kaplan*, 789 F.2d 1574, 229 U.S.P.Q. 678, 681 (Fed. Cir. 1986). Domination, by itself, does not give rise to double patenting. *Id.* Furthermore, an obviousness-type double patenting rejection must be based on what is *claimed* in the referenced patent. The Patent Office accordingly may not use the specification of the referenced patent to support an obviousness-type double patenting rejection. *Id.*, 229 U.S.P.Q. at 681-683; see also M.P.E.P. 804. For example, in *In re Kaplan*, the Federal Circuit held that an application claiming the use of a solvent mixture was not properly rejected for obviousness-type double patenting over a patent claiming the use of a solvent and disclosing examples of solvent mixtures in the specification, but not *claiming* the use of a solvent mixture. *In re Kaplan*, 229 U.S.P.Q. at 683-684. Thus, even if pending claim 48 "embraces" the subject matter of the claims of the '106 patent, as alleged by the Patent Office, that allegation alone is insufficient to support a rejection for obviousness-type double patenting over the '106 patent claims.

As such, the Patent Office has improperly rejected claim 48 under the judicially created doctrine of obviousness-type double patenting, and the rejection should be withdrawn.

*Discussion of Provisional Obviousness-Type Double Patenting Rejections*

Claim 48 has been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 69-78 of U.S. Patent Application No. 09/321,797 ("the '797 application"). The '797 application has been allowed. This rejection is traversed for the reasons set forth below.

Claims 69-73 of the '797 application are directed to a system comprising an adenoviral vector deficient in one or more essential gene functions of the E1 region of the adenoviral genome and a deficiency in one or more essential gene functions in either or both of the E2A region and the E4 region of the adenoviral genome, and a cell that complements in *trans* for the deficiencies in such an adenoviral vector. Claims 74-78 are directed to a method of preparing an adenoviral vector.

In determining an obviousness-type double patenting rejection, the Patent Office must determine if the *claimed* invention of a patent application is in conflict with an invention *claimed* in a patent (M.P.E.P. 804). Claim 48 of the instant application is directed to a defective recombinant adenovirus wherein the *whole of the E4 region* of the adenoviral genome of is deleted. The claims of the '797 patent application do not teach or suggest a complete deletion of the entire E4 region of the adenoviral genome. Nevertheless, the Patent Office contends that instant claim 48 is not patentably distinct from claims 69-78 of the '797 application when read in light of Example 4. As set forth above, an obviousness-type double patenting rejection must be based on what is *claimed* in a referenced patent or patent application, and the Patent Office may not use the specification of the referenced patent or patent application to support an obviousness-type double patenting rejection. *In re Kaplan*, 229 U.S.P.Q. at 681-683; M.P.E.P. 804. As such, the Patent Office has improperly provisionally rejected claim 48 under the judicially created doctrine of obviousness-type double patenting, and the rejection should be withdrawn.

The remaining provisional obviousness-type double patent rejections involve pending patent applications (i.e., U.S. Patent Application Nos. 08/258,416, 09/261,922, 09/766,405, and/or 09/934,207). According to M.P.E.P. § 804, a provisional obviousness-type double patenting rejection is proper unless the provisional rejection is the only rejection remaining in one of the applications. The other obviousness-type double patenting rejections set forth in the Office Action have been addressed herein such that these remaining provisional obviousness-type double patenting rejections are the only remaining rejections in the instant

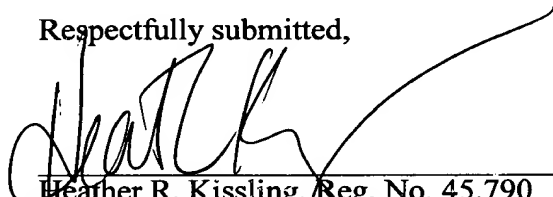
In re Appln. of Kovesdi et al.  
Application No. 09/964,065

application. Accordingly, these remaining provisional rejections should be withdrawn in the instant application.

*Conclusion*

The application is considered in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned agent.

Respectfully submitted,



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Date: October 11, 2002

CERTIFICATE OF MAILING

I hereby certify that this RESPONSE TO OFFICE ACTION (along with any documents referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Box AF, Washington, D.C. 20231.

Date: Oct. 11, 2002





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RESPONSE UNDER 37 CFR 1.116 ECH CENTER 1600/2900  
EXPEDITED PROCEDURE  
EXAMINING GROUP 1632

PATENT  
Attorney Docket No. 213257

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Kovesdi et al.

Application No. 09/964,065

Art Unit: 1632

Examiner: Priebe, S.

Filed: September 26, 2001

For: COMPLEMENTARY  
ADENOVIRAL VECTOR  
SYSTEMS AND CELL LINES

AMENDMENTS TO THE TITLE AND THE CLAIMS  
IN RESPONSE TO OFFICE ACTION DATED AUGUST 14, 2002  
(deletions indicated by brackets, additions indicated by underlining)

*Amendments to the title:*

[COMPLEMENTARY] REPLICATION-DEFICIENT ADENOVIRAL VECTOR  
AND PLASMID WITH ADENOVIRAL COMPONENT [SYSTEMS AND CELL LINES]

*Amendments to the claims:*

48. (Twice Amended) A defective recombinant adenovirus that (a) requires, for replication, complementation *in trans* of one or more essential gene functions of an E1 region and an E4 region of an adenovirus genome, and (b) comprises an adenoviral genome wherein all or part of the E1 region and the whole of the E4 region, and optionally all or part of an E3 region, is deleted from the adenoviral genome.

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52. (New) The defective recombinant adenovirus of claim 50, wherein all or part of the E3 region is deleted.